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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/539,160	06/14/2005	Thomas Gradel	190-89	2690

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WILLIAM H. EILBERG
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SUITE 501 WEST
BALA CYNWYD, PA 19004

EXAMINER

SAN MIGUEL, ANITZA M

ART UNIT	PAPER NUMBER
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3733

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/26/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/539,160

Applicant(s)

GRADEL ET AL.

Examiner

Anitza M. San Miguel

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 June 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 14-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 14-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 June 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 6/14/2005.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

Priority

If applicant desires to claim the benefit of a prior-filed application under 35 U.S.C. 120, a specific reference to the prior-filed application in compliance with 37 CFR 1.78(a) must be included in the first sentence(s) of the specification following the title or in an application data sheet. For benefit claims under 35 U.S.C. 120, 121 or 365(c), the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of the applications.

If the instant application is a utility or plant application filed under 35 U.S.C. 111(a) on or after November 29, 2000, the specific reference must be submitted during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. If the application is a utility or plant application which entered the national stage from an international application filed on or after November 29, 2000, after compliance with 35 U.S.C. 371, the specific reference must be submitted during the pendency of the application and within the later of four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) or sixteen months from the filing date of the prior application. See 37 CFR 1.78(a)(2)(ii) and (a)(5)(ii). This time period is not extendable and a failure to submit the reference required by 35 U.S.C. 119(e) and/or 120, where applicable, within this time period is considered a waiver of any benefit of such prior application(s) under 35 U.S.C. 119(e), 120, 121 and 365(c). A benefit claim filed after the required time period may be accepted if it is accompanied by a grantable

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petition to accept an unintentionally delayed benefit claim under 35 U.S.C. 119(e), 120, 121 and 365(c). The petition must be accompanied by (1) the reference required by 35 U.S.C. 120 or 119(e) and 37 CFR 1.78(a)(2) or (a)(5) to the prior application (unless previously submitted), (2) a surcharge under 37 CFR 1.17(t), and (3) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Director may require additional information where there is a question whether the delay was unintentional. The petition should be addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

If the reference to the prior application was previously submitted within the time period set forth in 37 CFR 1.78(a), but not in the first sentence(s) of the specification or an application data sheet (ADS) as required by 37 CFR 1.78(a) (e.g., if the reference was submitted in an oath or declaration or the application transmittal letter), and the information concerning the benefit claim was recognized by the Office as shown by its inclusion on the first filing receipt, the petition under 37 CFR 1.78(a) and the surcharge under 37 CFR 1.17(t) are not required. Applicant is still required to submit the reference in compliance with 37 CFR 1.78(a) by filing an amendment to the first sentence(s) of the specification or an ADS. See MPEP § 201.11.

Specification

The disclosure is objected to because of the following informalities:

In page 5, lines 24, reference "2" refers to the "upper larger face" and "upper larger wall" (page 5, line 13). The examiner recommends applicant to be consistent with the terminology.

In page 5, lines 24-25, reference "3" refers to the "lower larger face" and "lower larger wall" (page 5, line 14). The examiner recommends applicant to be consistent with the terminology.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 14-19, 21-23 and 26 are rejected under 35 U.S.C. 102(e) as being anticipated by Jackson (Reference Pub. No.: 2002/0068976 A1).

Jackson discloses an intervertebral implant (1) comprising a solid biocompatible material implant body (5) having a tubular general structure delimited by an upper wall (15) and a lower wall (16), two opposite lateral walls (see Figure 1 below) that are plane and slightly divergent toward the front, and a posterior wall (17) with a threaded axial hole (50), with a single interior cavity (see Figure 1 below; paragraph 0036) providing

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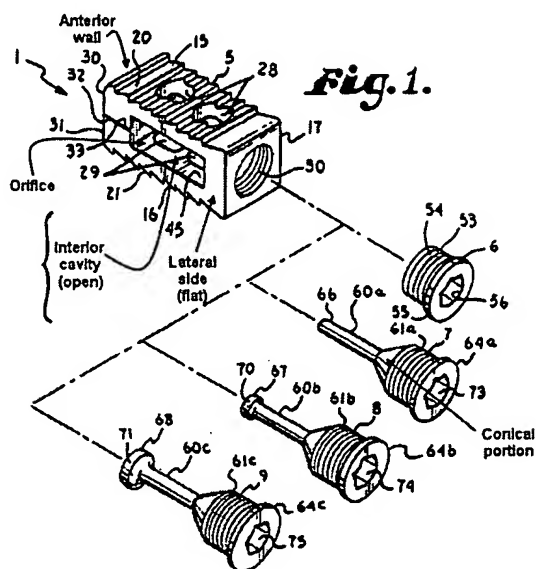
communication between orifices provided in the upper wall (15) and the lower wall (16), wherein: the upper (15) and lower (16) wall each comprise a respective single large upper or lower orifice (45, 46), an interchangeable compression plug (6, 7, 8, 9; paragraph 0034); the interior cavity is closed toward the front by an anterior wall (see Figure 1 below), the width of the implant (1) defined by the lateral walls is less than its height defined by the upper and lower wall. It is noted that Jackson's implant could also be cylindrical in shape (paragraph 0011), therefore allowing the width of the implant to be less than its height. Because of the upper and lower orifice, the interior cavity is open over the whole of its width between the lateral walls and over the whole of its length between the posterior and anterior wall (see Figure 1 below).

The interchangeable compression plug (6, 7, 8, 9) comprises a conical interior end portion (see Figure 1 below). The interchangeable compression plug (6, 7, 8, 9) and the threaded axial hole (50) that receives it have a diameter substantially equal to the width of the interior cavity in the vicinity of the posterior wall (see Figure 1 below). The interchangeable compression plug (6, 7, 8, 9) has a length such that, at the end of screwing it into the threaded axial hole (50) that receives it, its interior end portion penetrates the interior cavity to a distance of at least one quarter of the length of said interior cavity (paragraph 0041-0043). The implant (1) has at least two interchangeable compression plugs (6, 7, 8, 9; paragraph 0034) having different lengths (paragraph 0041). The anterior wall includes an eccentric threaded hole of smaller diameter (paragraph 0038). The upper and lower larger wall include annular toothed anti-expulsion ribs (paragraph 0037). The interchangeable compression plug is made of

titanium (paragraph 0011). The upper (15) and lower wall (16) are each of conical general shape and the upper and lower orifice are each bordered at their anterior and posterior ends by a flat perpendicular to the lateral walls (see Figure 1 below).

It is noted that Jackson's invention is used between a pair of adjacent vertebrae in order to provide stabilization between the vertebrae that has been destabilized due to injury. Also, the "expandible member" disclosed by Jackson is capable of compressing the implant into the vertebrae and therefore stabilizing the vertebrae. It is further noted that Jackson discloses that in some circumstances different members of windows may be provided in the upper and lower walls. Therefore, Jackson's implant could have a single orifice instead of two smaller orifices.

With regard to the statements of intended use and other functional statements, they do not impose any structural limitations on the claims distinguishable over Jackson (i.e. "adapted to be fitted by screwing it into the threaded axial hole in the posterior wall"), which is capable of being used as claimed if one so desires to do so. *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Furthermore, the law of anticipation does not require that the reference "teach" what the subject patent teaches, but rather it is only necessary that the claims under attack "read on" something in the reference. *Kalman v. Kimberly Clark Corp.*, 218 USPQ 781 (CCPA 1983). Furthermore, the manner in which a device is intended to be employed does not differentiate the claimed apparatus from prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987).



The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 1 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jackson (Reference Pub. No.: 2002/0068976 A1) in view of Schläpfer et al. (Reference U.S. Patent “6,059,829”).

Jackson discloses the claimed invention except for the upper and lower wall being convex and slightly divergent toward the front and the posterior wall of the implant including an external diametral groove. Schläpfer et al. (herein Schläpfer) teaches to provide the upper and lower wall being convex and slightly divergent toward the front (col. 2, lines 6-23) in order for the implant to have an overall lens shape. Schläpfer

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further teaches to provide the posterior wall of the implant including an external diametral groove (col. 3, lines 38-42) in order to grip the implant by an instrument and it is possible to apply a rotational torque via the instrument directly to the implant. It would have been obvious to one skill in the art at the time the invention was made to construct the device of Jackson having the upper and lower wall being convex and slightly divergent toward the front and the posterior wall of the implant including an external diametral groove, in view of Schläpfer, in order for the implant to have an overall lens shape, in terms of the upper and lower wall being convex, and in order to grip the implant by an instrument and it is possible to apply a rotational torque via the instrument directly to the implant.

Claims 24 and 25 rejected under 35 U.S.C. 103(a) as being unpatentable over Jackson (Reference Pub. No.: 2002/0068976 A1) in view of Schläpfer et al. (Reference U.S. Patent "6,059,829") and further in view of Brantigan (Reference U.S. Patent "5,425,772").

The combination of Jackson and Schläpfer discloses the claimed invention except for the implant body made of a PEEK type polymer and the implant comprising titanium marker in the implant body away from the interchangeable compression plug. Brantigan teaches to provide an implant made of a PEEK type polymer (col. 3, lines 47-57) in order to reduce the affects of the compression and for promoting better bone fusion. Brantigan further teaches to provide the titanium markers in the implant body in order to visualization of postoperative bone healing. It would have been obvious to one skilled in the art at the time the invention was made to construct the device of the

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combination of Jackson as modified by Schlöpfer, having the implant body made of a PEEK type polymer and having titanium marker, in view of Brantigan, in order to reduce the affects of the compression, promote bone growth and for visualization of postoperative bone healing.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See PTO-892 for cited art of interest.

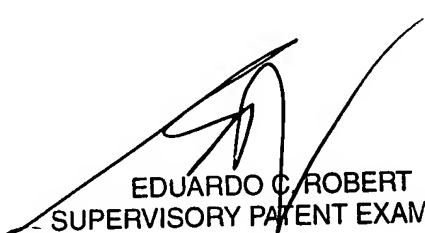
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anitza M. San Miguel whose telephone number is 571-272-3279. The examiner can normally be reached on 8:00 am - 5:30 pm EST (M-F).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ASM



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